Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12523

0 - FRONT

COMPLAINT/INJURY REPORT

1. COMPLAINT NUMBER: DAL7-4819 12523

2. DATE OF COMPLAINT (Month/Day/Year): 8/16/97

3. FORM OF COMPLAINT: (1) ☐ TELEPHONE (3) ☐ VISIT (2) ☐ LETTER

4. SOURCE OF COMPLAINT: (1) ☒ CONSUMER (3) ☐ TRADE SOURCE (2) ☐ GOVERNMENT ☐ L ☐ S ☐ F (4) ☐ OTHER (Indicate in Remarks)

5. COMPLAINANT IDENTIFICATION

a. NAME AND ADDRESS (Include Zip Code): [redacted]

b. AREA CODE AND TELEPHONE NO.
HOME [redacted]
WORK

6. COMPLAINT OR INJURY

a. DESCRIPTION OF COMPLAINT/INJURY
See letter dated 8/16/97 from [redacted] to FDA. (attached)

b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT?
(1) ☒ NO (2) ☐ YES (Explain in Remarks)

7. INJURY OR ILLNESS RESULTED (1) ☐ NO (2) ☐ YES (If "YES" complete Items a through d)

a. EIB (HFC-161) NOTIFIED (1) ☐ NO (2) ☐ YES DATE

b. TYPE SYMPTOMS — ONSET (HR.)
1 ☐ VOMITING
2 ☐ NAUSEA
3 ☐ DIARRHEA
4 ☐ FEVER
5 ☐ SKIN/EYE IRR.
6 ☐ HEADACHE
7 ☒ OTHER Weight Loss months [redacted]

c. ATTENDING HEALTH PROFESSIONAL
(1) ☐ NO (2) ☐ YES (If "yes" give name, address, and phone no.)
[redacted]

d. HOSPITALIZATION REQUIRED
(1) ☐ NO (2) ☐ YES (If "yes" give name, address, phone no. and dates)

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8. PRODUCT AND LABELING

a. BRAND NAME: Herbal Balance

b. PRODUCT NAME: Herbal Diet Supplement

c. SIZE AND PACKAGE TYPE: 180 capsule plastic container

d. NAME AND LOCATION OF STORE WHERE PURCHASED: [redacted]

e. PACKAGE CODE/SERIAL NUMBER/ETC.: 123701
EXP/USE BY DATE: 5/99

f. DATE PURCHASED: 7/19/97

g. PRODUCT USED (If "yes" enter date) (1) ☐ NO (2) ☒ YES

h. AMT REMAINING: 1 jar

9. MANUFACTURER/ DISTRIBUTOR OF PRODUCT

a. HOME DISTRICT: Florida

b. C.F. NO.: 1058134

c. NAME AND ADDRESS OF FIRM (Include Zip Code):
Dist by Slim for Life, Inc.
Plantation, FL 33313
Product of Canada

d. IMPORT PRODUCT (1) ☐ NO (2) ☐ YES

10. EVALUATION AND DISPOSITION

a. PROBLEM KEYWORD (1) CODE: RX (2) DESCRIPTION: Reaction

b. EVALUATION
(1) ☐ NOT AN FDA OBLIGATION
(2) ☐ OBLIGATION, NO VIOLATION
(3) ☐ FDA ACTION INDICATED
(4) ☐ INSUFFICIENT INFORMATION UNABLE TO EVALUATE

c. DISPOSITION
(1) ☐ IMMEDIATE FOLLOW-UP
(2) ☐ F/U NEXT EI
(3) ☐ CLOSED WITHOUT FURTHER INVESTIGATION
(4) ☐ REFERRED TO OTHER FEDERAL AGENCY (Closes file)
(5) ☐ REFERRED TO STATE/ LOCAL AGENCY (Closes file)
(6) ☐ REFERRED TO OTHER FDA_____DISTRICT

11. PRODUCT CODE: 54FCG09

12. INFORMATION COPIES TO:
☐ HFN - 355 (Biologics) ☐ HFZ - 343
☐ HFZ - 400
☐ HFN - 730 ☐ HFC - 161
☐ HFN - 333 ☐ _____
☐ HFV - 236

REMARKS

97 SEP 19 A7:06

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NAME AND TITLE: Amy Johansen, CSO

RECEIVED
CLINICAL RESEARCH
& REVIEW/OSN HFS-452

DATE: 8/16/97

FORM FDA 2516 (4/85)

#DAL7-4819

August 16, 1997

Food + Drug Administration

Enclosed is my letter to [redacted] which will explain my reason for contacting your office.

Your help in investigating [redacted] will be greatly appreciated as this is a most serious matter

[redacted]

Phone: [redacted]
FAX:

000002

[redacted]

Phone: [redacted]
FAX

August 16, 1997

[redacted]

This letter is to demand that you take all Herbal Balance from your centers as of this day. When I joined [redacted] I weighed 143 lbs, with a goal of 130 lbs. The young lady who signed me up was adament that the herbs she sold me were not drugs. Later on my friend [redacted] said, [redacted] those herbs are not right." I still thought the Herbal Balance was just that Herbs. In July Readers Digest came out with an article telling how very dangerous this herb is . I bought another jar of Herbal Balance around July 19th at the cost of $140.00, before I found out about the article.
As I write this, I weigh 115 lbs. My health is ruined, my nerves are shattered, and I'm likened to an addict with withdrawal since being off the Herbal Balance. I have pneumonia, can do nothing, and cannot sleep at night. It seems strange that [redacted] didn't get some kind of information on the dangers of this herb and warn their customers.

I must insist that you stop at this moment selling Herbal Balance and warn anyone who is taking it. I have about $1000.00 in this which I wish to be refunded. I will send the herbs back to you.
If you do not get rid of this product further action will be taken as I will prevent you from killing or making someone very ill. I'm afraid it will take a long time to regain my health due to the fact that I cannot gain weight or sleep. I wish there were tighter controls for businesses like yours, but it comes down to greed and I hope ignorance on your part. Your clinic had me so convinced that the Herbal Balance was just harmless herbs, that I tried to get others to take the herbs.

Enclosed is the article from Readers Digest dated July, 1997. I lost from 143 lbs. to 115 lbs. as of July 28, 1997. If this letter of intent fails, I will have no other alternative but to try to close your clinics down.

[redacted]
Former [redacted] ember
[redacted]

cc Food and Drug Administration
cc Channel [redacted] News
cc Senator Kay Bailey Hutchison
cc State Rep. [redacted]
cc [redacted]

000003

Adverse Reaction Questionnaire

Complaint Number: DAL7-4819 Investigator: Amy Johansen

Consumer Information

Date of Report: 12/23/97 MM/DD/YY

Initial Report Source: ☒ORA Consumer Injury
☐Telephone ☒Correspondence ☐MedWatch
☐USP ☐PQRS ☐Poison Control ☐CDC

Name [redacted] Gender: ☒F ☐M Age:

Race: ☒1-White ☐2-Black ☐3-Asian/Pacific Islander ☐4-Native American ☐5-Hispanic
☒8-Other ☐9-Unknown

Information on Adverse Reaction

Date of Adverse Reaction: 7/28/97 1st time to take it
Previous Reaction to Product Type: ☐Yes ☒No

Give the site of consumption/ingestion (e.g. home, restaurant, office): Home & Office

The following information relates to the consumers' use of the product.

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms):
Fast beating heart - as soon as she started eating - as long as she took meds
Weight loss - 9 months - kept losing after eating use
Pneumonia - 7/97 - duration = 5 weeks
Coolant sleep great - cried a lot after abating use
How long did the symptoms last? See above
Give the circumstances of exposure (i.e. how much was taken, how was the product taken and how often was it taken, etc.).
2 tablets by mouth once a day for nine months.

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event:
Herbal Balance [redacted] foods as well as other foods
Generic multivitamin

Did event abate after use of suspected product stopped or dose reduced: ☐Yes ☒No ☐Unknown
Did symptoms reoccur after reintroduction of suspected product: ☐Yes ☐No ☐Unknown ☒Not Applicable
Did symptoms reoccur after using other products with the same ingredients: ☐Yes ☐No ☐Unknown ☒Not Applicable

Medical Information

Was a health care provider seen?: ☒Yes ☐No
Give health care provider's name, address and telephone number: [redacted]

Occupation of Health Care Provider: ☒MD both doctors ☐Osteopath ☐Naturopath ☐Nurse ☐Pharmacist
☐Other (specify) _____

What medical tests were performed and what were the results?
Chest X-ray, blood work - not conclusive for Legionairres Disease
What was the medical diagnosis? pneumonia
What treatment(s) was given (e.g., drugs, other)?
Antibiotics, mood elevators

Were there any preexisting condition(s)/treatment(s)?
(If YES, list them including allergies, and chronic diseases): ☐Yes ☒No

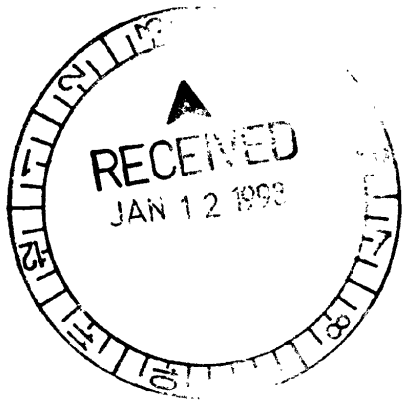
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

HOUSTON RESIDENT POST
MEMORANDUM

DATE January 6, 1998

FROM Amy Johansen, CSO



SUBJECT CFSAN Project #12523

TO Dale L. Graham

As per the subject CFSAN project, copies of the complainant's medical records are attached. They are to be forwarded to the CFSAN ARMS Monitor, Bridgette M. Wallace. When I receive the medical records from the other doctor, I will forward them to her through you.

Endorsement:

To: Bridgette M. Wallace, CFSAN ARMS Monitor
HFS-636

Copies of complainant's medical records are attached, as requested.

Dale L. Graham
Supervisory Consumer Safety Officer
Houston Resident Post